

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

Application Number	10/585,611
Filing Date	11-Jul-2006
First Named Inventor	SIEGEL, Steven
Art Unit	1615
Examiner Name	
Attorney Docket Number	P-7562-US

Sheet 1 of 10

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A	US-4,883,666	11-28-1989	Sabel, et al.	
	B	US-5,601,835	02-11-1997	Sabel, et al.	
	C	US-6,130,200	10-10-2000	Brodbeck, et al.	
	D	US-6,166,173	12-26-2000	Mao, et al.	
	E	US-5,629,008	05-13-1997	Lee	
	F	US-5,665,428	09-09-1997	Cha, et al.	
	G	US-5,817,343	10-06-98	Burke	
	H	US-5,871,778	02-16-1999	Kino, et al.	
	I	US-4,989,463	11-23-1999	Tracy, et al.	
	J	US-6,004,573	12-21-1999	Rathi, et al.	
	K	US-6,117,949	09-12-2000	Rathi, et al.	
	L	US-6,143,314	11-07-2000	Chandrashekar	
	M	US-6,201,072	03-13-2001	Rathi, et al.	
	N	US-5,770,231	06-23-1998	Jean Mesens, Wechelderzande	
	O	US-6,544,559	04-08-2003	Jean Mesens, Wechelderzande	
	P	US-6,368,362	04-09-2002	Ronald Pedemonte, et al.	
	Q	US-6,110,921	08-29-2000	Jean Mesens, Wechelderzande	
	R	US-5,965,168	10-12-1999	Jean Mesens, Wechelderzande	
	S	US-6,803,055	10-12-2004	Jean Mesens, Wechelderzande	
	T	US-5,792,477	08-11-1998	Michael Rickey, et al.	
	U	US-5,654,008	08-05-1997	J. Michael Ramstack	
	V	US-2002-017909A1	12-05-2002	Siegel, et al.	
	W	US 4,351,337	09-28-1982	Sidman	

FOREIGN PATENT DOCUMENTS

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	X	WO 94/10982	05-26-1994	Kino, et al.		<input type="checkbox"/>
	Y	EP 669128	01-05-2000	Kino, et al.		<input type="checkbox"/>

Examiner Signature	/Danah Al-awadi/	Date Considered	07/18/2010
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			Art Unit	1615	
Sheet	2	of	10	Examiner Name	
				Attorney Docket Number	P-7562-US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.†	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	1	ADAMS CE, Fenton MK, Ouraishi S, David AS (2001) Systematic meta-review of depot antipsychotic drugs for people with schizophrenia. Br J Psychiatry 179:290-299.	<input type="checkbox"/>	
	2	ANDERSON, et al. (1997) Biodegradation and biocompatibility of PLA and PLGA microspheres. Adv Drug Delivery Rev 28:5-24	<input type="checkbox"/>	
	3	AYUSO-GUTIERREZ, et al. (1997) Factors influencing relapse in the long-term course of schizophrenia. Schizophr Res 28:199-206.	<input type="checkbox"/>	
	4	BENELLI, et al. (1998) Clonazepam microencapsulation in poly-D, L-lactide-co-glycolide microspheres. J. Microencapsulation 15(4):431-443.	<input type="checkbox"/>	
	5	BOCCUZZI et al. (2001) Utilization of oral hypoglycemic agents in a drug-insured U.S. population. Diabetes Care. Aug;24(8):1411-5.	<input type="checkbox"/>	
	6	BUCKLAND, et al. (1993) Both splicing variants of the dopamine D2 receptor mRNA are up-regulated by antipsychotic drugs. Neurosci Lett 150:25-28.	<input type="checkbox"/>	
	7	CHEN, et al. (2005) Microarray analysis of differentially expressed genes in rat frontal cortex under chronic risperidone treatment. Neuropsychopharmacology 30:268-277.	<input type="checkbox"/>	
	8	CHENG, et al. (1998) A poly (D,L-lactide-co-glycolide) microsphere depot system for delivery of haloperidol. J. Controlled Release 55(2-3):203-212.	<input type="checkbox"/>	
	9	CHENG, et al. (2000) Schizophrenia and Drug Delivery Systems. J Drug Targeting 8(2):107-117.	<input type="checkbox"/>	
	10	CHUI et al. (2003) Association between adherence to diuretic therapy and health care utilization in patients with heart failure. Pharmacotherapy. Mar;23(3):326-32.	<input type="checkbox"/>	
	11	CORRISS, et al. (1999) Interactive risk factors for treatment adherence in a chronic psychotic disorders population. Psychiatry Res 89:269-274.	<input type="checkbox"/>	

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	12	CERNANSKY (2003) Treatment of schizophrenia: preventing the progression of disease. Psychiatr Clin North Am 26:367-379.	<input type="checkbox"/>
	13	DASH, et al. (1998) Therapeutic applications of implantable drug delivery systems. J Pharmacol Toxicol Methods 40:1-12.	<input type="checkbox"/>
	14	DAVIS, et al. (2003) A meta-analysis of the efficacy of second-generation antipsychotics. Arch Gen Psychiatry 60:553-564.	<input type="checkbox"/>
	15	DORPH-PETERSEN, et al. (2004) Stereological analysis of the mediodorsal thalamic nucleus in schizophrenia: volume, neuron number, and cell types. J Comp Neurol 472:449-462.	<input type="checkbox"/>
	16	ELMER, et al. (1996) Cocaine cross-sensitization to dopamine uptake inhibitors: unique effects of GBR12909. Pharmacol Biochem Behav 53:911-918.	<input type="checkbox"/>
	17	FISCHEL-GHODSIAN, et al. (1993) Analysis of drug release kinetics from degradable polymeric devices. J Drug Target. 1(1):51-57.	<input type="checkbox"/>
	18	FOSS, et al. (2004) Development of acrylic-based copolymers for oral insulin delivery. Eur J Pharm Biopharm 57:163-169.	<input type="checkbox"/>
	19	FOSTER AND GOA (1998) Risperidone. A pharmaco-economic review of its use in schizophrenia. Pharmacoeconomics. Jul;14(1):97-133.	<input type="checkbox"/>
	20	FRANK, et al. (2005) Controlled release from biodegradable polymers: effect of drug type and polymer composition. J Controlled Release 102:333-344.	<input type="checkbox"/>
	21	FREIBERG AND ZHU (2004) Polymer microspheres for controlled drug release. Int J Pharm. Sep 10;282(1-2):1-18	<input type="checkbox"/>
	22	GANDER, et al. (2001) Polymers as a platform for drug delivery: Reviewing our current portfolio on poly(lactide-co-glycolide) (PLGA) microspheres. CHIMIA 55:212-217.	<input type="checkbox"/>

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	23	GEDDES, et al. (2000) Atypical antipsychotics in the treatment of schizophrenia: systematic overview and meta-regression analysis. <i>BMJ</i> 321:1371-1376.	<input type="checkbox"/>
	24	GOSS, et al. (1991) Haloperidol treatment increases D2 dopamine receptor protein independently of RNA levels in mice. <i>Life Sci</i> 48:1015-1022.	<input type="checkbox"/>
	25	GRAYSON, et al. (2005) Size and temperature effects on poly(lactic-co-glycolic acid) degradation and microreservoir device performance. <i>Biomaterials</i> 26:2137-2145.	<input type="checkbox"/>
	26	HARRISON AND GOA (2004) Long-acting risperidone: a review of its use in schizophrenia. <i>CNS Drugs</i> ; 18(2):113-32.	<input type="checkbox"/>
	27	HELLER, (1979) Controlled drug release by polymer dissolution. II: Enzyme-mediated delivery device. <i>J Pharm Sci</i> 68(7):919-21.	<input type="checkbox"/>
	28	HIGUCHI T., (1961) Rate of release of medicaments from ointment bases containing drugs in suspensions. <i>J. Pharm. Sci.</i> 50:874-875.	<input type="checkbox"/>
	30	HOLY, et al. (2001) Optimizing the sterilization of PLGA scaffolds for use in tissue engineering. <i>Biomaterials</i> 22:25-31.	<input type="checkbox"/>
	31	HUSSAIN (2001) Fluorometric method for the simultaneous quantitation of differently-sized nanoparticles in rodent tissue. <i>Int J Pharm</i> 214:55-61.	<input type="checkbox"/>
	32	IRANI, et al. (2004) Patient attitudes towards surgically implantable, long-term delivery of psychiatric medicine. <i>Neuropsychopharmacology</i> 29:960-968.	<input type="checkbox"/>
	33	JAIN, et al. (2000) Controlled delivery of drugs from a novel injectable in situ formed biodegradable PLGA microsphere system. <i>J Microencapsulation</i> 17(3):343-62.	<input type="checkbox"/>

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	34	JEONG, et al. (2003) Preparation of poly(DL-lactide-co-glycolide) microspheres encapsulating all-trans retinoic acid. Int J Pharm 259:79-91.	<input type="checkbox"/>	
	35	KANE (1999) Olanzapine in the long-term treatment of schizophrenia. Br J Psychiatry Suppl: (37) 26-29.	<input type="checkbox"/>	
	36	KANE, et al. (1998) Guidelines for depot antipsychotic treatment in schizophrenia. European Neuropsychopharmacology Consensus Conference in Siena, Italy. Eur Neuropsychopharmacol 8:55-66.	<input type="checkbox"/>	
	37	KANE, et al. (2002) Efficacy and safety of aripiprazole and haloperidol versus placebo in patients with schizophrenia and schizoaffective disorder. J Clin Psychiatry 63:763-771.	<input type="checkbox"/>	
	38	KAROW, et al. (2002) Subjective well-being and quality of life under atypical antipsychotic treatment. Psychopharmacology (Berl) 162:3-10.	<input type="checkbox"/>	
	39	KEEFE, et al. (2004) Comparative effect of atypical and conventional antipsychotic drugs on neurocognition in first-episode psychosis: a randomized, double-blind trial of olanzapine versus low doses of haloperidol. Am J Psychiatry 161:985-995.	<input type="checkbox"/>	
	40	KEITH, et al. (2003) Partial compliance and patient consequences in schizophrenia: our patients can do better. J Clin Psychiatry 64:1308-1315.	<input type="checkbox"/>	
	41	KITCHELL, et al. (1985) Poly (lactic/glycolic acid) biodegradable drug-polymer matrix systems. Methods Enzymol. 112:436-48.	<input type="checkbox"/>	
	42	KLAVON, et al. (1990) Insertion site complications during the first year of NORPLANT use. Contraception 41:27-37.	<input type="checkbox"/>	
	43	KNABLE, et al. (1997) Extrapyramidal side effects with risperidone and haloperidol at comparable D2 receptor occupancy levels. Psychiatry Res 75:91-101.	<input type="checkbox"/>	
	44	KNEGTERING, et al. (2005) Predominant role of the 9-hydroxy metabolite of risperidone in elevating blood prolactin levels. Am J Psychiatry 162:1010-1012.	<input type="checkbox"/>	

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	45	KOHLER, et al. (1994) A new animal model of dopamine supersensitivity using s.c. implantation of haloperidol releasing polymers. Neuroscience Letters 170(1):99-102	<input type="checkbox"/>
	46	KULKARNI, et al. (1971) Biodegradable poly(lactic acid) polymers. 5(3):169-81.	<input type="checkbox"/>
	47	KUSUMI, et al. (2000) Differential effects of subchronic treatments with atypical antipsychotic drugs on dopamine D2 and serotonin 5-HT2A receptors in the rat brain. J Neural Transm 107:295-302.	<input type="checkbox"/>
	48	LAMBERT, et al. (2003) Pharmacological approaches to the management of schizophrenia. Med J Aust 178 Suppl: S57-61.	<input type="checkbox"/>
	49	LAROBINA, et al. (2002) Mechanistic understanding of degradation in bioerodible polymers for drug delivery. AICHE J 48:2960-2970.	<input type="checkbox"/>
	50	LELAS, et al. (2004) Anxiolytic-like effects of the corticotropin-releasing factor1 (CRF1) antagonist DMP904 [4-(3-pentylamino)-2,7-dimethyl-8-(2-methyl-4-methoxyphenyl)-pyrazolo-[1,5-a]-pyrimidine] administered acutely or chronically at doses occupying central CRF1 receptors in rats. J Pharmacol Exp Ther 309:293-302.	<input type="checkbox"/>
	51	LEWIS, et al. (2001a) Lamina-specific deficits in parvalbumin-immunoreactive varicosities in the prefrontal cortex of subjects with schizophrenia: evidence for fewer projections from the thalamus. Am J Psychiatry 158:1411-1422.	<input type="checkbox"/>
	52	LEWIS, et al. (2001b) Service use and costs of treating schizophrenia with atypical antipsychotics. J Clin Psychiatry 62:749-756.	<input type="checkbox"/>
	53	LEYSEN, et al. (1994) Risperidone: a novel antipsychotic with balanced serotonin-dopamine antagonism, receptor occupancy profile, and pharmacologic activity. J Clin Psychiatry 55 Suppl:5-12.	<input type="checkbox"/>
	54	LI, et al. (1996) Hydrolytic degradation of poly (D,L-lactic acid) in the presence of caffeine base. J. Control. Release 40:41-53.	<input type="checkbox"/>

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	56	LINHARDT (1989) "Biodegradable Polymers for Controlled Release of Drugs" <i>Controlled Release of Drugs</i> , Rosoff, Ed., New York: VCH Publishers, Chapter 2, p. 53-83.	<input type="checkbox"/>
	57	LU ET AL. (2000) In vitro and in vivo degradation of porous poly(DL-lactic-co-glycolic acid) foams. <i>Biomaterials</i> . Sep; 21(18):1837-45.	<input type="checkbox"/>
	58	MARTIN, et al. (2003) Clinical experience with the long-acting injectable formulation of the atypical antipsychotic, risperidone. <i>Curr Med Res Opin</i> 19:298-305.	<input type="checkbox"/>
	59	MCCOMBS, et al. (1999) Use patterns for antipsychotic medications in medicaid patients with schizophrenia. <i>J Clin Psychiatry</i> 60 Suppl 19:5-11; discussion 12-13.	<input type="checkbox"/>
	60	MCQUADE, et al. (2004) A comparison of weight change during treatment with olanzapine or aripiprazole: results from a randomized, double-blind study. <i>J Clin Psychiatry</i> 65 Suppl 18:47-56.	<input type="checkbox"/>
	61	MELTZER (1995) The role of serotonin in schizophrenia and the place of serotonin-dopamine antagonist antipsychotics. <i>J Clin Psychopharmacol</i> 15:2S-3S.	<input type="checkbox"/>
	62	MENZIN, et al. (2003) Treatment adherence associated with conventional and atypical antipsychotics in a large state medicaid program. <i>Psychiatr Serv</i> 54:719-723.	<input type="checkbox"/>
	63	METZGER, et al. "Pharmacokinetic and behavioral characterization of a long-term antipsychotic delivery system in rodents and rabbits" <i>Psychopharmacology (Berl)</i> . 2007 Feb; 190(2):201-11.	<input type="checkbox"/>
	64	MILLER-CHOU, et al. (2003) A reviews of polymer dissolution. <i>Progress Pol Sci</i> 28:1223-1270.	<input type="checkbox"/>
	65	NARASIMHAN, et al. (1997) Molecular analysis of drug delivery systems controlled by dissolution of the polymer carrier. <i>J Pharma Sci</i> 86:297-304.	<input type="checkbox"/>

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Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/585,611
				Filing Date	11-Jul-2006
				First Named Inventor	SIEGEL, Steven
				Art Unit	1615
				Examiner Name	
(use as many sheets as necessary)				Attorney Docket Number	P-7562-US
Sheet	8	of	10		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	66	NASRALLAH, et al. (2002) Efficacy, safety, and tolerability of quetiapine in patients with schizophrenia. J Clin Psychiatry 63 Suppl 13:12-20.	<input type="checkbox"/>	
	67	NASRALLAH, et al. (2004) Atypical antipsychotics and metabolic dysregulation: evaluating the risk/benefit equation and improving the standard of care. J Clin Psychopharmacol 24:S7-14.	<input type="checkbox"/>	
	68	NATSUGOE, et al. (1960) Controlled Release of Cisplatin Incorporated into Biodegradable Poly-D, L-Lactic Acid. Anticancer Research 17(3C):1957-60.	<input type="checkbox"/>	
	69	NYBERG, et al. (1996) Positron emission tomography of in-vivo binding characteristics of atypical antipsychotic drugs. Review of D2 and 5-HT2 receptor occupancy studies and clinical response. Br J Psychiatry Suppl 40:4-44.	<input type="checkbox"/>	
	70	OKADA, et al. (1995) Biodegradable microspheres in drug delivery. Crit Rev Ther Drug Carrier Syst 12:1-99.	<input type="checkbox"/>	
	71	PANYAM, et al. (2003) Biodegradable nanoparticles for drug and gene delivery to cells and tissue. Adv Drug Delivery Rev 55:329-347.	<input type="checkbox"/>	
	72	RAMASWAMY, et al. (2004) Aripiprazole possibly worsens psychosis. Int Clin Psychopharmacol 19:45-48.	<input type="checkbox"/>	
	73	REEVES, et al. (2004) Worsening schizoaffective disorder with aripiprazole. Am J Psychiatry 161:1308.	<input type="checkbox"/>	
	74	REUSS, et al. (2001) Atypical neuroleptic drugs downregulate dopamine sensitivity in rat cortical and striatal astrocytes. Mol Cell Neurosci 18:197-209.	<input type="checkbox"/>	
	75	ROBINSON, et al. (2002) Predictors of medication discontinuation by patients with first-episode schizophrenia and schizoaffective disorder. Schizophr Res 57:209-219.	<input type="checkbox"/>	
	76	RON, et al. (1991) "Erodible Systems" Treatise on Cont. Drug Del. 199-217.	<input type="checkbox"/>	

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	77	ROSKOS, et al. (1997) "Degradable controlled release systems useful for protein delivery" in Protein Delivery: Physical Systems, Sanders and Hendren eds., Plenum press, New York, Chapter 2, 45-92.	<input type="checkbox"/>
	78	SABEL, et al. (1990) Levodopa delivery from controlled-release polymer matrix: delivery of more than 600 days in vitro and 225 days of elevated plasma levels after subcutaneous implantation in rats. J Pharmacol Exp Ther 255:914-922.	<input type="checkbox"/>
	79	SARMA, et al. (1995) Neurovascular injury during removal of levonorgestrel implants. Am J Obstet Gynecol 172:120-121.	<input type="checkbox"/>
	80	SCHOTTE, et al. (1996) Risperidone compared with new and reference antipsychotic drugs: in vitro and in vivo receptor binding. Psychopharmacology (Berl) 124:57-73.	<input type="checkbox"/>
	81	SEEMAN MV (2001) Clinical trials in psychiatry: do results apply to practice? Can J Psychiatry 46:352-355.	<input type="checkbox"/>
	82	SHARMA, et al. (2003) Cognitive function in schizophrenia. Deficits, functional consequences, and future treatment. Psychiatr Clin North Am 26:25-40.	<input type="checkbox"/>
	83	SIEGEL (2007) Extended release drug delivery strategies in psychiatry: Theory to practice. Psychiatry.	<input type="checkbox"/>
	84	SIEGEL, et al. (2002) Surgically implantable long-term antipsychotic delivery systems for the treatment of schizophrenia. Neuropsychopharmacology 26:817-823.	<input type="checkbox"/>
	85	SIEGEL, et al. (2006) Effect of drug type on the degradation rate of PLGA Matrices. Eur J Pharm Biopharm. 64(3):287-93.	<input type="checkbox"/>
	86	SIEPMANN, et al. (2001) Mathematical modeling of bioerodible, polymeric drug delivery systems. Adv Drug Delivery Rev 48:229-247.	<input type="checkbox"/>
	87	SIMPSON, et al. (2004) Randomized, controlled, double-blind multicenter comparison of the efficacy and tolerability of ziprasidone and olanzapine in acutely ill inpatients with schizophrenia or schizoaffective disorder. Am J Psychiatry 161:1837-1847.	<input type="checkbox"/>
	88	STRAKOWSKI, et al. (2003) Atypical antipsychotics in the treatment of bipolar disorder. Expert Opin Pharmacother 4:751-760.	<input type="checkbox"/>
	89	SUNG, et al. (1998) Controlled release of nalbuphine prodrugs from biodegradable polymeric matrices: influence of prodrug hydrophilicity and polymer composition. Int. J. Pharm. 172:17-25.	<input type="checkbox"/>
	90	SVARSTAD, et al. (2001) Using drug claims data to assess the relationship of medication adherence with hospitalization and costs. Psychiatr Serv 52:805-811.	<input type="checkbox"/>

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	91	SWAINSTON HARRISON, et al. (2004) Aripiprazole: a review of its use in schizophrenia and schizoaffective disorder. <i>Drugs</i> 64:1715-1736.	<input type="checkbox"/>
	92	SWERDLOW, et al. (1994) Assessing the validity of an animal model of deficient sensorimotor gating in schizophrenic patients. <i>Arch Gen Psychiatry</i> 51:139-154.	<input type="checkbox"/>
	93	TARAZI, et al. (2002) Long-term effects of olanzapine, risperidone, and quetiapine on serotonin 1A, 2A and 2C receptors in rat forebrain regions. <i>Psychopharmacology (Berl)</i> 161:263-270.	<input type="checkbox"/>
	94	TEICH (2003) Side effects of ziprasidone. <i>Am J Psychiatry</i> 160:1355-1356.	<input type="checkbox"/>
	95	VELLIGAN, et al. (2003) Psychopharmacology: perspectives on medication adherence and atypical antipsychotic medications. <i>Psychiatr Serv</i> 54:665-667.	<input type="checkbox"/>
	96	VISCO, et al. (1999) Observed patient compliance with a structured outpatient bladder retraining program. <i>Am J Obstet Gynecol</i> 181:1392-1394.	<input type="checkbox"/>
	97	WADA, et al. (1991) In vitro evaluation of sustained drug release from biodegradable elastomer. <i>Pharm Res.</i> 8(10):1292-1296.	<input type="checkbox"/>
	98	WANG, et al. (2000) Synthesis, characterization, biodegradation, and drug delivery application of biodegradable lactic/glycolic acid polymers: I. Synthesis and characterization. <i>J Biomater Sci Polym Ed.</i> 11(3):301-18.	<input type="checkbox"/>
	99	YASUI-FURUKORI, et al. (2001) Different enantioselective 9-hydroxylation of risperidone by the two human CYP2D6 and CYP3A4 enzymes. <i>Drug Metab Dispos</i> 29:1263-1268.	<input type="checkbox"/>
	100	ZHENG, et al. (1998) High-performance liquid chromatography-mass spectrometry-mass spectrometry analysis of morphine and morphine metabolites and its application to a pharmacokinetic study in male Sprague-Dawley rats. <i>J Pharm Biomed Anal</i> 16:971-980.	<input type="checkbox"/>
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